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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 11/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,743

Applicant(s)

FLYGARE ET AL.

Examiner

Tamthom N. Truong

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8. 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims pending in the application are 1-5, 8-16, 18, 19, 27, 30, 32-34, 36, 37, 39-41, 43-46, 48, 49, 54-67, 69-73, 79, 80, 83, 84, 87, 89, 90, and 92 .

Continuation of Disposition of Claims: Claims rejected are 1-5, 8-16, 18, 19, 27, 30, 32-34, 36, 37, 39-41, 43-46, 48, 49, 54-67, 69-73, 79, 80, 83, 84, 87, 89, 90 and 92.

DETAILED ACTION

Applicant's amendment of 9-15-03 has been fully considered. Claims 6, 7, 17, 20-26, 28, 29, 31, 35, 38, 42, 47, 50-53, 68, 74, 75, 77, 78, 81, 82, 85, 86, 88, 91, 93, and 94 have been cancelled. Thus, only claims 1-5, 8-16, 18, 19, 27, 30, 32-34, 36, 37, 39-41, 43-46, 48, 49, 54-67, 69-73, 79, 80, 83, 84, 87, 89, 90, and 92 are pending.

Applicant's argument has obviated the rejection of 112/2nd paragraph for claims 9-11, and 66-68. Thus, the rejection for said claims is withdrawn herein. However, the argument has not overcome the 112/2nd rejection for **claims 36, 37, 39, 40, 89, 90, and 92. Thus, the 112/2nd rejection for those claims is maintained herein.**

Claims 38, 47, 68, 91, and 94 have been cancelled, therefore, the previous rejections for said claims have been rendered moot.

Since no terminal disclaimer was filed, **the non-statutory obviousness-type double patenting rejection remains outstanding.** However, the statutory double patenting rejection is withdrawn herein because claims 6, 7, 17, 20-26, 28, 29, 31, 35, 38, 42, 50-53, 68, 74, 75, 77, 78, 81, 82, 85, 86, 88, 91, and 93 have been cancelled.


Although the limitation of "substituted or unsubstituted aryl (C1-C4)heteroalkyl" is deleted from claims 1 and 61, the teaching of Sato et. al. stills anticipates those claims. Hence, the previous 102(b) rejection is maintained herein. Also, new relevant prior arts are found which prompt the following new art rejections.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 36, 37, 39, 40, 89, 90, and 92 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claim 36 depends on claim 2, and recites R^1 and R^2 to form a ring. However, claim 2 recites R^2 as a monovalent group (e.g., aryl, heteroaryl), and not the group of . Thus, the dependency of claim 36 is unclear. It appears that claim 36 should be dependent on claim 1. Claims 37, 39, and 40 are rejected as being dependent on claim 36.
- b. Claim 89 recites R^1 and R^2 forming a 5- or 6-membered heterocyclic ring with the nitrogen atom of NR^1R^2 . However, claim 89 depends on claim 61 which requires a group E to connect R^1 and R^2 . Thus, claim 89 lacks antecedent basis for omitting group E.
- c. Claim 90 depends on claim 89, and recites R^1 and R^2 to form an optionally substituted indole. However, claim 89 recites R^1 and R^2 to form a 5- or 6-membered heterocyclic ring, which suggests a monocycle, and not a bicycle. Thus, claim 90 lacks antecedent basis.
- d. Claim 92 depends on claim 89, and recites R^1 and R^2 to form an optionally substituted 1,2,3,4-tetrahydroquinoline. However, claim 89 recites R^1 and R^2 to form a 5-

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or 6-membered heterocyclic ring, which suggests a monocycle, and not a bicycle. Thus, claim 92 lacks antecedent basis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-5, 8, 12-16, 18, 19, 27, 30, 32-34, 41, 43-46, 48, 49, 54-65, 69-73, 76, 79, 80, 83, 84, and 87 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 2, 5-10, 21, 24, 26, 28, 30-34, 36, 40-55, 58, and 63 of U.S. Patent No. 5,880,151. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons stated in the previous office action.

3. Claims 1-3, 9-11, 36, 37, 61, 62, 66, and 67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, and 6-9 of U.S. Patent No. 6,121,304. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reason stated in the previous office action.

4. Claims 1, 30, 43, 44, and 54-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 3-14 of U.S. Patent No. 6,316,484. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reason stated in the previous office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 12, 15, 16, 61-63, 69, 72, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by **Mohrs et. al.** (US 5,093,340). The Example 77 on column 43 discloses a compound that reads on the instant formula I with the following substituents:

- i. Y is SO₂; Z is –NR¹R²;
- ii. Either R¹ or R² is hydrogen, and the other is a phenyl group substituted with a substituted alkoxy.

The claimed compound inhibits thrombocyte aggregations, therefore, the teaching of Mohrs et. al. also anticipates the instant composition claims as well.

6. Claims 1, 61, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

- a. **Lardy et. al.** (US 5,387,709): See Table IIId, compound of Example No. 100a (on columns 89 and 90);
- b. **Bigg et. al.** (US 5,385,931): See compounds 24a and 24 on column 40;
- c. **Sato et. al.** (EP 469,901): See compound #81 on page 19.

7. The above references disclose compounds that read on the instant formula I with the following substituents:

- i. Y is SO₂; Z is -NR¹R²;
- ii. Either R¹ or R² is hydrogen, and the other is a substituted alkyl group, or a substituted (C2-C6)heteroalkyl group.

8. Claims 61 and 62 are rejected under 35 U.S.C. 102(b) as being inherently anticipated by **Wilkes et. al.** (US 4,900,867). The two intermediates of formula (I) with substituents listed on column 5 of US'867 read on the instant formula I with the following substituents:

- i. Y is SO₂; Z is -NR¹R²;
- ii. Either R¹ or R² is hydrogen, and the other is a substituted alkyl group.

Note, the first proviso in claim 61 does not exclude the instant where R² is hydrogen, and R¹ is substituted alkyl group. Another words, said proviso limits R², but not R¹.

9. Claims 61 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by **Pews et. al.** (US 5,591,503). The compound listed on line 35 of column 2 reads on the instant formula I with the following substituents:

- i. Y is SO₂; Z is -NR¹R²;
- ii. Both R¹ and R² are independently an alkyl group.

Although the compound of Pews et. al. has a different use, it still anticipates the instant formula I because compounds of similar structure is assumed to have the same activity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 43-45, and 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mohrs et. al.** (US'340) in view of **Witte et. al.** (US 4,443,477).

As discussed in the above 102 rejection, Mohrs et. al. discloses a compound that is embraced by the instant formula I. Said compound has a different utility because it inhibits

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thrombocyte aggregations, and not affecting lipoprotein or cholesterol in the blood. However, such difference can be overcome by the teaching of **Witte et. al.** (US'477).

Witte et. al. discloses a generic formula of substituted phenylsulfonamide, which possesses a lipid-depressing activity. Because the compound of Mohrs et. al. is also a substituted phenylsulfonamide as that of Witte et. al., one of the ordinary skill in the art would have been motivated to use Mohrs' compound in "depressing" lipid and cholesterol, which in turn treats diseases related to high level of lipid and/or cholesterol as claimed herein.

Thus, at the time of the invention, it would have been obvious to treat a disease related to high level of lipid or cholesterol in the blood in view of the combined teachings above.

In light of the above rejections, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1st -03.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

November 26, 2003



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